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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATTERSON, CHARLES L JR	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,496	ADNEY ET AL.	
	Examiner	Art Unit	
	Charles L. Patterson, Jr.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2005 and 22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-16,20-22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) *9,10,12,15,16,20-22,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8,11 and 26* is/are rejected.

7)☒ Claim(s) *13,14,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

In applicants' amendment of 6/22/06 they ask on page 2 that "the attached Sequence Listing (total 27 pages) [be substituted] for the corresponding Sequence Listing previously submitted in the Application...[and that a] computer readable form is also provided on a floppy disk, which is identical to the printed copy". There was no written sequence listing attached to this amendment or any of the other papers filed on 6/22/06 petitioning to revive the abandoned application, etc. Nor has there been another CFR submitted to the office. There was a sequence disclosure submitted 5/6/03 with 4 sequences, another sequence listing submitted on 3/8/04 with 120 sequences, another sequence disclosure submitted 4/21/04 with 120 sequences and one submitted 11/26/04 with 96 sequences. There are apparently only 96 sequences listed in the substitute specification and the sequence disclosure submitted 11/26/04 is the sequence disclosure of record at this time in the application. If these are not the correct sequence then applicant should submit another sequence disclosure.

The amendment filed 6/22/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicants state that they are adding "all sequences contained in the Sequence Listing" to the substitute specification and that these "[r]eference to prior applications and referral to some sequences had been inadvertently omitted in previous filings and have now been added pursuant to 37 C.F.R. 1.57(a)" (page 12 of applicants' Remarks). 37 CFR 1.57(a) deals with incorporation by reference and states that if a foreign, provisional or interna-

tional application was filed and "the inadvertently omitted portion of the specification or drawings(s) is completely contained in the prior-filed application, the claim under § 1.55 or § 1.78 shall be considered an incorporation by reference of the prior application as to the inadvertently omitted portion of the specification or drawing(s)". The section goes on to require an amendment of the specification to include the inadvertently omitted portion be made, that "a copy of the prior-filed application" be supplied and that "the inadvertently omitted portion of the specification...[be identified as to where it] can be found in the prior-filed application" (37 CFR § 1.57(a)(1)(i)-(iii). It is presumed that PCT/US00/19007 or 60/143,711 are the prior application and a copy of these application are of record in the instant application file or available to the examiner. However, applicants do not identify where the additions to the substitute specification such as SEQ ID NOs are found in these applications and looking at the applications it is not readily apparent to the examiner. Apparently SEQ ID NO:5 was not included in the priority applications as filed and apparently both of these priority document only had 4 sequences disclosed. Looking at Figure 1 of this application, apparently SEQ ID NO:5 is a translation of this nucleotide sequence, which is apparently SEQ ID NO:4. This should be stated by applicants. The other sequences appear to have been disclosed in this application, not in a priority document. If this is the fact then this should be stated by applicants.

Applicant is required to cancel the new matter in the reply to this Office Action. Either the substitute specification must be cancelled or else it must be pointed out specifically where the instant additions are supported by one of the priority documents or the original specification of this application.

Applicant's election with traverse of Group 1, claims 6-8, 11, 13-14, 24 and 26 limited to a substitution of Pro at position 8 of SEQ ID NO:5 in the reply filed on 6/22/06 is acknowledged. The traversal is on the grounds that: (1) The "requirement is illegal because it contravenes the statutory mandate in 35 U.S.C. § 112, paragraph six permitting Applicant to claim what has been discovered as a means…[and that] [t]he respective species are related as the claimed means and so are not independent and distinct within the meaning of 35 U.S.C. § 121…because the species share a common functionality and because they represent the discloses embodiments for accomplishing that functionality". (2) Claim 6 is a generic, linking claim because it recites a means and pursuant to MPEP § 803.03(b) that means that claim 6 may be elected for examination and other claims in the application must be rejoined if the linking claim is found allowable and that "there is no statutory or other basis for the requirement as stated because the inventions as grouped by the Office are not independent and distinct as is required to invoke 35 § 121". (3) "The requirement for restriction further contravenes Patent Office policy as enunciated in MPEP § 803.04 which states that, as to individual sequences, the policy is to permit examination of at least ten such sequences in a individual application." (4) "These sequences are all related a mutations to the same base sequence of the same wild-type gene under different functional rationales…[and] [s]ince it is a statutory requirement that the inventors must claim what *they* regard as the invention, it would be more appropriate for the office to allocate a restriction as to these species than to artificially contrive a separate invention for each substitution that is allocated to the same functional purpose…[and that] [s]ince claim 6 is generic, this requirement if restated would have to be stated as an election of

species and not as a restriction" (emphasis in original). (5) Claims 15m 16, 27 and 38 are "directed to an exoglucanase bearing the sequence changes mediated by the primers as defined by SEQ ID NO:71, 74 or 77 and combination thereof…[and that] such a small number of nucleotide sequences would fall within the reasonable limit stipulated in 37 C.F.R § 1.141."

This is not found persuasive because:

(1) It is maintained that the instant claims are not "claimed means" but rather separate and distinct products that have a different sequence and are thus structurally distinct. The claims are not drawn to "a combination" as in 35 USC § 112 sixth paragraph but are drawn to distinct mutations of SEQ ID NO:5. Only part (g) mentions a "combination" and that is "any combination of the mutations of (a)…[through](f)". As to the meaning of "independent and distinct", in MPEP § 802.01 the meaning of "independent" and "distinct" is discussed, along with a discussion of the legislative history of these terms in patent law. It is concluded in MPEP § 803 that restriction is proper when the inventions "are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - 806.05(i))"(emphasis added).

(2) While claim 6 may be construed as being "linking", although the exact meaning of this term is hard to understand. At least claim 6 is a generic claim and should be allowable if all the other requirements of patentability are met. However, the claims that are dependent from it are not construed as claims that must be examined under Markush rules because each and every distinct mutation is structurally different from the other and therefore the claims are properly restricted and not subject to an election of species.

(3) MPEP § 803.03(b) states that "up to ten independent and distinct nucleotide sequences will be examined". One sequence is "up to ten" and it

is maintained that to examine more sequences would be a serious burden upon the examiner. Furthermore, the office restricts the examiner to a search of one sequence unless there are extenuating circumstances. The examiner searched SEQ ID NO:5 with Pro substituted at position 8. To search all of the other sequences (inventions 1-45) would entail 44 additional searches plus all of the combinations.

(4) As discussed regarding (2) *supra*, the inventions are properly restricted as each mutated sequence is structurally distinct.

(5) To start with, claims 16 and 17 have been amended to change the SEQ ID NO. Secondly, SEQ ID NO:71, 74 and 77 are structurally different nucleotides and to examine these along with the other groups would entail a serious burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-10, 12, 15-16, 20-22 and 27-28 and claims 6-8, 11, 13-14 and 24-26 not drawn to a Pro at position 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/22/06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is drawn to a nucleic acid encoding a variant cellobiohydrolase, SEQ ID NO:5, that is mutated to improve the functionality of the variant cellobiohydrolase with respect to the wild-type cellobiohydrolase. The claim thus includes the very broad embodiments of any mutation that will improve any functionality, such as solubility, pH tolerance, salt tolerance, thermostability, etc. The specification does not teach one of ordinary skill in the art how to produce all of the mutations that will improve any or all of the functionalities of the enzyme. Therefore, applicants should limit the claim to the embodiments taught in the specification.

Claims 7-8, 11 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-8, 11 and 26 are confusing in that they contain embodiments that were not elected for prosecution.

The examiner has re-read the specification and all of the previous actions in the application. It was decided that the previous 35 USC § 101 and 112 rejections should not be repeated for these claims. Applicants' remarks in the paragraph labeled "Claim Rejections 35 U.S.C §101" in the amendment filed 7/28/05 are not understood. The examiner has tried to find the specific references to pages and lines in both the original specification and substitute specification and cannot find them. Applicants must be looking at a different version of the specification than the examiner. It is noted that the substitute specification omitted the line numbering that was in the orig-

inal specification. However, the first generic part of the specification (such as page 2, lines 23-24 in the substitute specification) states that an "object of the invention is to provide improved thermal tolerant variants of the cellobiohydrolase enzyme capable of functioning at increased process temperatures" and the heading to Table 2 is "Proline mutations to improve thermal tolerance". Therefore, since this table contains the mutant S8P, it is considered that this mutant has utility.

Claims 13-14 and 24-25 are objected to as being dependent upon rejected base claims. The instant claims limited to Pro substituted at position 8 would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the

Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
October 17, 2006